510(k) SUMMARY

Submitter: Michael Smith
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Date Prepared: July 07, 2000

Device Information:

Trade/Proprietary Name:	Rosetta-Lt/Rosetta-Rx
Common Name:	Modulator/Demodulator, Data Translator
Classification Name:	Not Known

Predicate Device Information:

Trade/Proprietary Name:	GEMS Series 2000 (Modified DR-2C/PMC 100)
Common Name:	EMS Communications Console
Manufacturer	General Devices (same as applicant)
Classification:	Class II
510(k) No.	K896153
Trade/Proprietary Name:	GEMSCOM Series 3000 & 12 Lead ECG Option
Common Name:	EMS Field Radio
Manufacturer	General Devices (same as applicant)
Classification:	Class II
510(k) No.	K914889A & K921929/A

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DESCRIPTION OF DEVICE

The Rosetta-Lt & Rosetta-Rx provide a means for communicating physiologic information (waveforms and data) over standard communications means, such as 2-way radio, landline or wireless (cellular) telephone, from a pre-hospital location to a hospital.

The Rosetta-Lt inputs ECG & data acquired by a standard monitor/defibrillator and "translates" or converts this information to modulation and/or data formats suitable for transmission over common communications means. The acquired information is input to the Rosetta-Lt via a patch cable and the converted information is output to the communications means via a patch cable or by acoustic coupling.

The Rosetta-Rx either as a stand-alone device or as an option card for the GEMS Series 2000 console, receives information transmitted from the Rosetta-Lt and converts the information into an analog or digital form suitable for presentation by standard visual or printout presentation means. As a stand-alone device, the information is input via a connection to the communications means and presentation is via a standard laser printer. When employed as an option card to the GEMS Series 2000, the information is input from the console and presentation means are via the console's CRT display, strip-chart recorder, and a standard laser printer.

Transmission formats employed by Rosetta devices include standard frequency modulation (FM) formats (currently standard for EMS applications), DTMF (touch-tone) signaling (commonly used for signaling in telecommunications), Frequency Shift Keying (FSK) (commonly used for data communication), as well as standard digital schemes, as used in digital communications systems.

INTENDED USE

The intended use for the Rosetta-Lt/Rosetta-Rx is to facilitate the transmission of ECG and/or other physiologic information acquired from a standard monitor/defibrillator in an EMS pre-hospital setting, back to a physician at hospital via standard communication means, such as 2-way radio, landline or wireless telephone.

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PERFORMANCE COMPARISON WITH PREDICATE DEVICE

FUNCTION SPECIFICATION	GEMSCOM 3000	ROSETTA-LT
Function	Modulates ECG waveforms into FM transmissio format	Modulates ECG waveforms & data into FM & FSK transmission format
Communication Means	Radio, landline telephone, wireless telephone	Radio, landline telephone, wireless telephone
Acquisition Device Connection	Integral (digital) and external hardwire (analog)	Hardwire (digital and analog)
Transmission Device Connection	Integral for radio. Hardwire and acoustic coupling for radio, landline or wireless telephone	Hardwire and acoustic coupling for radio, landline or wireless telephone
Modulation Means	Hardware	Hardware/Software
ECG Modulation Format	1400 Hz Center frequency, 50 mV/Hz deviation	1400 Hz Center frequency, 50 & 250 mV/Hz deviation
Data & Signaling Format	DTMF	DTMF, FSK & Serial
Self-Calibrating	No	Yes
Form Factor	Hand-carried	Handheld
Power Source	Internal 14V Battery, External 12V	Internal 9V Battery, External 12V

FUNCTION SPECIFICATION	GEMS SERIES 2000	ROSETTA-RX
Function	Demodulates FM ECG waveforms	Demodulates FM ECG waveforms & FSK Data
Presentation Means	CRT & Strip-Chart Recorder	GEMS 2000 & laser printer (option card) laser printer (stand alone)
Communication Means	Radio, landline telephone, wireless telephone	Radio, landline telephone, wireless telephone
PC Interface	RS-232	RS-232
Demodulation Means	Hardware	Hardware/Software
ECG Modulation Format	1400 Hz Center frequency, 50 mV/Hz deviation	1400 Hz Center frequency, 50 & 250 mV/Hz deviation
Data & Signaling Format	DTMF & Serial	DTMF, FSK & Serial
Self-Calibrating	No	Yes
Form Factor	Desktop cabinet	Card for GEMS Series 2000 (option card) Desktop cabinet (stand alone version)
Power Source	120 VAC, 50/60 Hz	GEMS Series 2000 (option card) External 12VDC wall adapter (stand alone version)

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SUMMARY OF DIFFERENCES

The differences between the predicate and the new devices relate primarily to the introduction of additional modulation and data formatting techniques and the use of a laser printer as additional presentation means. Other differences include those related to specific implementation (circuits, software), the incorporation of a stand-alone version for the receive side, size, battery type, appearance and minor operating features.

SUMMARY OF NON-CLINICAL TESTS

The Rosetta-Lt and Rosetta-Rx were subjected to non-clinical testing to insure proper performance. The testing consisted of the following parts:

- A determination of the ability of the Rosetta-Lt to correctly and accurately acquire desired information from the acquisition device under simulated use conditions
- A determination to ability of the Rosetta-Lt to correctly convert the gathered information to the desired communications scheme under simulated use conditions
- A determination of the efficacy of the intended transmission schemes under simulated use conditions
- A determination of the ability of the Rosetta-Rx to correctly and accurately acquire the information from the transmission means under simulated use conditions
- A determination to ability of the Rosetta-Rx to correctly convert the gathered information for presentation by the desired presentation means and accurately present this information under simulated use conditions

DISCUSSION OF HOW TEST RESULTS SUPPORT SUBSTANTIAL EQUIVALENCY

The testing that was performed on the Rosetta-Lt and the Rosetta-Rx demonstrate that the system is substantially equivalent to the predicate devices in that physiologic information acquired by an external source was reliably and accurately converted to a format suitable for transmission over a common transmission means, reliably and accurately communicated by this means, and then reliably and accurately reconstructed for presentation at the far end.

CONCLUSION DRAW BY NON-CLINICAL TESTING

The conclusions draw by the non-clinical testing indicate that the Rosetta-Lt/Rosetta-Rx successfully perform the intended task under normal use conditions. The system behaved as expected and demonstrates the application of well-understood technology as well as the absence of any electrical risk factors to the patient.

END OF SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2000

Mr. Michael Smith
President
General Devices
1000 River St.
Ridgefield, NJ 07657

Re: K002089
Rosetta-Lt and Rosetta-Rx Data Translators
Regulatory Class: II (two)
Product Code: 74 DRG .
Dated: October 5, 2000
Received: October 10, 2000

Dear Mr. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the

Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

6.2

INDICATIONS FOR USE STATEMENT

PMN 510(k) Number: K00 2089

Device Name: Rosetta-Lt/Rosetta-Rx

Indications For Use:

The Rosetta-Lt/Rosetta-Rx is indicated for use whenever it is desired to transmit ECG and/or other physiologic information acquired from a standard monitor/defibrillator in an EMS pre-hospital setting, back to a physician at hospital via standard communication means, such as 2-way radio, landline or wireless telephone.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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